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Statement

October 3, 2000

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Senator Tim Hutchinson Testifies on Need for GOCO Vaccine Production Facility

Senator Tim Hutchinson, chairman of the Senate Armed Services Personnel Subcommittee, made the following statement today before the House Government Reform Committee:

"Chairman Burton, Mr. Waxman, members of the Committee, thank you for inviting me to testify this morning. While my efforts in the Senate have not focused on the Anthrax Vaccine Immunization Program with the laser-like focus of the Committee on Government Reform, the excellent body of work you have compiled complements my efforts to change the Department of Defense's vaccine acquisition strategy. You see, it is my belief that the BioPort/anthrax debacle provides lawmakers with an excellent case study, one which illustrates that the Department's present policy of relying on the private sector to provide vaccines critical to the protection of our men and women in uniform is fatally flawed and must be changed. There exists a growing consensus that the Department of Defense must shoulder the responsibility and begin to produce biological warfare vaccines for itself.

In the Early 1990's, in the aftermath of the Gulf War, recommendations were presented to senior Defense Department acquisition officials to fulfill the urgent demands of war-fighters to develop vaccines against biological agents. One of the principal recommendations was for the construction of a Government-Owned, Contractor-Operated (GOCO) vaccine production facility. Detailed and thoughtful studies presented many merits to the GOCO approach. Without listing all of its merits, I will point out that the GOCO option would guarantee the country access to a vaccine supply immune from the foibles of a profit-driven pharmaceuticals industry.

For reasons that remain a mystery to this day, the Defense Department did not elect to pursue the safer, GOCO option. Rather, the Department chose to contract with a private-sector entity we now know as BioPort, for the vaccine against the biological agent anthrax.

Since embarking on this acquisition strategy, events have proceeded as many had feared they would; disastrously. Last summer, the Defense Department awarded the BioPort corporation extraordinary contract relief to a previous contract for the production and vulnerable storage of the anthrax vaccine. The terms of the contract relief reduced the number of doses of vaccine to be produced by one-half, charged the U.S. taxpayer almost three times as much as was originally negotiated, and provided BioPort with an interest-free loan of almost $20 million. BioPort officials have stated that even this may not constitute enough support. I question the fitness of whoever negotiated such a horrendous arrangement on behalf of the American taxpayer.

In July, because of BioPort's continuing troubles, the Department was forced to dramatically scale back the scope of Phase One of the immunization program because the rapid rate of vaccinations threatened to consume the last of the Department's stockpile of FDA approved vaccine. Now, only those personnel who are deployed to high-threat regions, such as the Persian Gulf and the Korean peninsula, will receive vaccinations. As it appears increasingly apparent that neither additional lots of vaccine, nor the new

production line in East Lansing, will receive FDA approval anytime soon even this dramatically reduced effort may completely exhaust the Department's supply of vaccine, leaving our troops vulnerable.

As the Department is preparing to transition into production of the first of more than a dozen new bio-war vaccines developed under the Joint Vaccine Acquisition Program, it was apparent to me that unless we wish to repeat the mistakes of the past, a new acquisition strategy is urgently needed.

Mr. Chairman, my colleagues and I on the Senate Armed Services Committee are making efforts to prevent the Defense Department from continuing to pursue a flawed acquisition strategy. Through oversight hearings and legislative provisions within the National Defense Authorization Bill, we are actively providing the Department with some much needed guidance.

On April 14th, I chaired the second of three Committee hearings on the topic of vaccine production. During that hearing, DOD personnel who had advocated the GOCO route in the early Nineties, and were overruled, were given the opportunity to testify. Their testimony is perhaps the most important the Committee has received all year on this topic.

At a third Committee hearing, conducted in July, the Department announced that it had published a solicitation for a second-source of the Anthrax vaccine. As the Department received only cursory inquiries from the pharmaceutical industry during the required thirty day period, this effort appears to have failed.

In response to the testimony received by the Committee, I drafted Section 221 of the Senate's Fiscal Year 2001 National Defense Authorization Bill. Section 221 requires the Secretary of Defense to conduct a reevaluation of the present vaccine acquisition strategy. The report will include an evaluation of the commercial sector to meet DOD's vaccine requirements and a design for a Government-Owned, Contractor-Operated vaccine production facility.

Section 221 also notes that a significant body of work regarding this topic was assembled in the early 1990's, including Project Badger, which recommended that a GOCO vaccine production facility be constructed at the Pine Bluff Arsenal in my home state of Arkansas.

I fully expect that my provision will be included in the Conference Report that we will soon send to the President for his signature.

In addition to hearings and legislative provisions, I have begun a dialogue with numerous personnel within the Office of the Secretary of Defense. I would be remiss if I did not mention the many productive conversations I have had with the Under Secretary of Defense, Rudy deLeon. Because Secretary deLeon is relatively new to his position and has little ownership over the flawed decisions of the past, he has been very willing to explore alternative acquisition strategies including the solution I favor: construction of a Government-Owned, Contractor-Operated vaccine production facility. As evidence of his commitment to find a solution, vaccine production was the first topic discussed by the Defense Resources Board, which Secretary deLeon chairs, when it met to begin its preparation of the Defense budget submission for Fiscal Year 2001.

I have encouraged Secretary deLeon to include $25 million in the FY02 Defense budget submission for R&D, in addition to $400 million in the next version of the Department's Fiscal Years Development Plan, to cover construction costs. To ensure that funding for this project does not come at the expense of other critically needed bio-defense programs, I will soon meet with the Director of OMB. I am hopeful that I can explore with Mr. Lew ways to increase the top-line of the Defense budget to cover the expense of this project.

Mr. Chairman, I thank you for holding this hearing. For too long DOD has pursued a flawed acquisition strategy that is a disservice to both the American taxpayer and our men and women in uniform. The Department must be weaned from its dependence on the private sector for the provision of critical biological warfare vaccines. I appreciate the opportunity to testify about this important topic, and share with you my efforts, experiences and insights."